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Simulated Patient Studies: An Ethical Analysis

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Context: In connection with health care reform, the U.S. Department of Health and Human Services commissioned a "mystery shopper," or simulated patient study, to measure access to primary care. But the study was shelved because of public controversy over "government spying" on doctors. Opponents of the study also raised ethical concerns about the use of deception with human subjects without soliciting their informed consent.

Methods: We undertook an ethical analysis of the use of simulated patient techniques in health services research, with a particular focus on research measuring access to care. Using a case study, we explored relevant methodological considerations and ethical principles relating to deceptive research without informed consent, as well as U.S. federal regulations permitting exceptions to consent.

Findings: Several relevant considerations both favor and oppose soliciting consent for simulated patient studies. Making research participation conditional on informed consent protects the autonomy of research subjects and shields them from unreasonable exposure to research risks. However, scientific validity is also an important ethical principle of human subjects research, as the net risks to subjects must be justified by the value to society of the knowledge to be gained. The use of simulated patients to monitor access is a naturalistic and scientifically sound experimental design that can answer important policy-relevant questions, with minimal risks to human subjects. As interaction between researchers and subjects increases, however, so does the need for consent.

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Conclusions: As long as adequate protections of confidentiality of research data are in place, minimally intrusive simulated patient research that gathers policy-relevant data on the health system without the consent of individuals working in that system can be ethically justified when the risks and burdens to research subjects are minimal and the research has the potential to generate socially valuable knowledge.

Keywords: research ethics, simulated patient studies, audit methodology, deceptive design, exceptions to consent, access to care, public health, health services.

Simulated customers—commonly called secret or mystery shoppers—have long been used for quality control purposes by retail establishments and other companies that serve the public. These mystery shoppers seek or use a company's own services and then report back to the quality control staff. Research using a similar technique was proposed in 2011 in anticipation of the large expansions in coverage by Medicaid and private insurance as a result of the Patient Protection and Affordable Care Act. The U.S. Department of Health and Human Services (DHHS) commissioned a study in which researchers posing as prospective patients would use a script to call doctors' offices and attempt to obtain appointments for primary or specialty medical care. The purpose was to better understand the extent to which new patients with Medicaid or private insurance could expect to gain access to medical care. Announcement of the proposed study in the *Federal Register* (*Federal Register*, April 28, 2011), followed by an article describing the study in the *New York Times*, triggered strong public criticism by some doctors and members of Congress (Pear 2011). One doctor remarked, "I don't like the idea of the government snooping. It's a pernicious practice—Big Brother tactics, which should be opposed." Another stated, "If federal officials are worried about access to care, they could help us. They don't have to spy on us." Echoing these sentiments, Senator Orrin Hatch (R-UT) declared that the Obama administration was "wasting taxpayer dollars to snoop into the care physicians are providing patients." In response to the public criticism, the plans for the research were dropped.

Although this controversy certainly had a political element, the question we address in this article is how such methods should be viewed from the perspective of research ethics, particularly with regard to the use of deception with human subjects without soliciting their informed

consent. Mystery shopper methods are not new in research, having been used to generate powerful evidence of negligent business practices that impact public health (Sorenson and Vittes 2003) and to document racial discrimination in fields such as real estate and mortgage lending (Fix and Struyk 1993; Ross et al. 2002; Turner et al. 2002; Turner and Ross 2005). Such methods have been used, as well, in health services research to measure access to and the timeliness of needed outpatient medical appointments (Asplin, Rhodes, and Levy 2005; Bisgaier and Rhodes 2011; Medicaid Access Study Group 1994; Rhodes et al. 2009), to study the consultation practices of pharmacists (Weiss et al. 2010), and to examine the prescribing practices of primary care physicians (Kravitz et al. 2005). But previous use does not answer the question of how such methods comport with ethical principles and the regulatory framework that applies to research involving human subjects.

Addressing this issue is now of particular concern, as we have relatively few reliable methods for measuring access to care. Gathering knowledge regarding access to care is relevant to current public policy, as both Medicaid and private insurance coverage will undergo major expansions under the Patient Protection and Affordable Care Act (2010, Pub. L. No. 111–148) (Rosenbaum 2011). While mystery shopper research using simulated patients adopts a naturalistic and scientifically sound study design, this mode of research raises ethical concerns relating primarily to the use of deception with human subjects without soliciting their informed consent. This article provides an ethical analysis of simulated patient techniques used for health services research, with a particular focus on research measuring access to care. To describe this ethical analysis, we present next a brief case study of one completed simulated patient study of access to health care.

A Case Study of a Simulated Patient Study of Access to Urgent Outpatient Medical Care

In 2002/2003, a group of emergency care health services researchers used simulated patients to measure access to outpatient primary care following a supposed emergency room visit for an urgent medical condition (Asplin, Rhodes, and Levy 2005). The aim was to evaluate the association between insurance status and access to needed outpatient medical care.

Research assistants posing as patients telephoned randomly selected clinics and medical practice groups in nine U.S. cities. The sampling frame from which they drew their random sample was the lists of primary care providers who were on the hospital emergency departments' "on call" rosters and were thus identified as having some obligation to provide follow-up care for emergency department patients who did not have a primary care physician. Using a standardized script, a trained research assistant presented herself to the receptionist answering the telephone as a patient who had been seen the previous night at the local hospital emergency room. She said she had been given this number and had been told to seek urgent follow-up medical attention. The researcher described herself according to one of three common clinical vignettes involving pneumonia, hypertension, or a possible ectopic pregnancy. The same researcher called the same practice twice with calls separated by several weeks; the only significant difference between the calls was the reported insurance status. Callers were randomly assigned to report either private insurance (Blue Cross/Blue Shield) or Medicaid or to explain that they were uninsured. If she was not given an appointment, the uninsured simulated patient asked how much it would cost to pay in full at the time of the visit. After receiving this information, she inquired if it would be possible to pay $20 initially and make arrangements for paying the balance over time. If the receptionist indicated a willingness to schedule an appointment, the simulated patient used a scripted response to cancel the appointment at the end of the call.

This simulated patient study was conducted without prior notice to the clinics and physicians' practices and without informed consent. Two institutional review boards (IRBs) approved the research with a "waiver" of consent, as permitted in the U.S. federal regulations governing human subjects research, which we discuss later in this article. To avoid inconveniencing the study subjects and health care providers, the research was designed to minimize the time spent on the telephone calls. At the conclusion of the study, a debriefing letter was sent to all the clinics and office practices in the larger sampling frame, explaining that they may or may not have been contacted as part of a research study. The debriefing letter also provided the study results.

We briefly summarize the study results to indicate the potential social value of the knowledge that can be gained from this type of research—an essential element of ethical assessment. Simulated patients posing with private insurance were more likely to be offered appointments than those

insured by Medicaid (64% vs. 34%) or than the uninsured who offered to pay a small amount initially and the balance over time (65% vs. 25%). There was no significant difference in the likelihood of receiving an appointment between those privately insured and those willing to pay in full at the visit (66% vs. 63%) (Asplin, Rhodes, and Levy 2005). The results revealed important primary care capacity issues, even among the fully insured patients, as well as disparities in access in accordance with insurance status and ability to pay. In sum, this study uncovered important knowledge about access to medical care following emergency room visits that was helpful to both the practice of emergency medicine and public policy.

Do Simulated Patient Studies Pose Legitimate Ethical Concerns?

From the perspective of traditional research ethics, it would seem obvious that simulated patient studies, which involve deceptive research interventions without consent, are ethically problematic. They contravene the basic norm that interventional research should proceed only on the basis of informed consent by research subjects or by surrogate decision makers for those subjects not capable of giving informed consent. However, research ethics is often discussed in a parochial context that raises ethical concerns that are disproportionate to the way in which people assess related activities outside the research setting (Wertheimer 2011). To evaluate the ethical significance of this departure from informed consent in simulated patient research, we compared this type of research with other, related activities outside the context of human subjects research. Our example is the use of mystery shopper techniques for quality improvement in service industries and the practice of restaurant reviews.

Mystery shoppers have been widely used in various industries, such as retail and hotel businesses, for evaluating the quality of customer service (Lazarus 2009). Marketing researchers disguised as customers visit such businesses to gather data to assess performance and to guide quality improvement. In the business world, employees are often informed in advance that they may be visited by mystery shoppers, although they are not told when the visit will take place. Typically, employees are

given evaluative feedback based on the results of the mystery shoppers' assessment.

Businesses and nonprofit institutions providing services to the public have a legitimate interest in—or even a responsibility for—evaluating the quality of services provided by employees, as do hospitals with regard to physicians with practice privileges (Baily et al. 2006). Employees expect to have their performance evaluated; having consented to employment, they arguably have no grounds for objecting to reasonable methods of employer-sponsored quality assessment. Mystery shopper techniques have obvious value in quality assessment by simulating naturalistic interactions between customers and service providers. Any concerns with the use of deception are obviated, or at least mitigated, by prior notice that mystery shopper techniques will be used for evaluating performance.

This legitimating context of employer authority and employee consent is not operative in simulated patient studies conducted by researchers who have no institutional connections with the research subjects and the health care practices evaluated by this type of research. While staff responsible for answering telephones in medical clinics and physicians' offices have consented (as part of their job) to take calls from members of the public, it does not seem reasonable to construe their consent to employment as authorizing researchers not affiliated with their employer to gather data from them while posing as patients seeking access to medical care. In summary, simulated patient studies of access to medical care, such as the study just described, are ethically distinct from employer-sponsored quality improvement projects.

Restaurant evaluations might also seem comparable to simulated patient research techniques from an ethical perspective. Restaurant reviewers, writers of restaurant guides, and travel writers all routinely evaluate food quality and service based on their experience of dining at restaurants. Many restaurant reviewers commonly use disguises and typically make reservations using a phony name. For their part, restaurant owners expect to receive such reviews and benefit from them financially when they are positive. By consenting to serve meals to diners, restaurant owners and staff cannot have any legitimate objections to the practice of restaurant reviewing by some of the diners who visit the restaurant. Indeed, some restaurants provide opportunities for all diners to evaluate the quality of their meals and the service through satisfaction forms provided at the time of payment. Likewise, many hospitals regularly pay independent survey firms to collect anonymous patient satisfaction

surveys (AMGA 2012; Press Ganey 2010). The key aspect of mystery shopper quality improvement projects that is lacking in simulated patient research is that there is a context of expectation and consent that legitimates the former but not the latter. Therefore, ethical comfort with using mystery shopper techniques in quality improvement projects and in the practice of restaurant reviews by unannounced reviewers is not sufficient to ground the ethical legitimacy of simulated patient studies.

Ethical Justification of Simulated Patient Research

Simulated patient studies of access to medical care pose two distinctive ethical problems: the use of deception and the absence of consent. Requirements for informed consent serve the well-being and protect the autonomy of research subjects. With respect to protecting well-being, making research participation conditional on informed consent protects people from unreasonable exposure to research risks. However, the simulated patient studies comparable to our case study pose, at most, minor risks to participants. More strongly in favor of consent to this type of research is a general principle of respecting autonomy, according to which people are entitled to a protected zone of control over their lives (and their property), such that others are prohibited from intervening or interacting within this zone without valid consent (Feinberg 1986). Thus, as a rule, medical interventions constitute a violation of bodily integrity and count legally as battery if they are performed without consent; likewise, interventional research with capacitated adult human subjects is (generally) impermissible without their informed consent. In other words, consent is *morally transformative*, making permissible those interventions that would be prohibited in the absence of consent (Kleinig 2010). A case can be made that in simulated patient studies without consent, there is no authorization by human subjects (e.g., receptionists answering telephone calls at clinics) of their research participation and this is therefore an infringement of their autonomy. The contrary argument would be that there is no infringement of the autonomy of the receptionists because they are conducting public, as opposed to private, business. They are not exercising discretion but are instead being paid to answer the phone and schedule appointments for whoever calls

in accordance with organizational policy. But being a research subject lies outside the receptionists' job description, thus raising the question of what legitimates researchers interacting with them for the purpose of research without their consent. Moreover, simulated patient studies also involve deception, which violates a moral rule against lying—for example, researchers posing as patients are lying about their medical situation and their need for a doctor's appointment. As such, simulated patient studies can be construed as violating the expectations of honesty that characterize normal human interactions in the medical workplace.

We argue that simulated patient studies require ethical justification in view of concerns regarding the absence of consent and the use of deception. Justification can be grounded in considerations of the social value of policy-relevant knowledge, scientific validity, and risk-benefit assessment.

Social Value of Simulated Patient Studies

Just as in other aspects of medical care, it is important that health policy be based on scientifically rigorous data. In biomedical research, the use of masking and concealed allocation, widely endorsed in randomized double-blind clinical trials, lends confidence to the interpretation of results. A well-designed simulated patient study observes the public behavior that is occurring in the health care marketplace. The deceptive design allows this to be done without changing that behavior because of the presence of an observer. When simulated patient studies are used to measure access to care, both the public and the providers benefit from understanding important capacity issues. In addition, information about disparities can inform policies designed to remediate inequity in the delivery of health care. Bisgaier and Rhodes (2011) identified two dimensions of disparity in access to needed specialty care for children who are publicly insured (Medicaid-CHIP), compared with those who are privately insured. Publicly insured children had both lower rates of realized appointments (33% compared with 89%) and longer wait times (forty-two days compared with twenty days) for needed outpatient specialty care for urgent medical conditions. The study verified and quantified deficiencies and capacity issues that had previously been reported only anecdotally. The results of such studies are easily understood and politically persuasive in garnering public support for policy changes.

Scientific Validity

A necessary condition for justifying interventional research that is deceptive or conducted without consent is to demonstrate that a scientifically valid answer to the research question is not possible or practicable unless the requirement of informed consent is waived. With respect to evaluating access to medical care, clinics and doctors' offices could be telephoned by survey researchers who identify themselves as such to inquire about their willingness to give appointments to patients depending on insurance status or ability to pay. The validity of results of such survey research would be questionable, however, as the reported responses may not reflect "real world" behavior in scheduling appointments. The survey respondents may decline to participate, or they may report socially desirable responses that do not correspond to actual practices. In contrast, simulated patient techniques offer the simulation under the controlled conditions of a live encounter with a prospective patient seeking a needed appointment, thus permitting unbiased assessment of the variables, such as insurance status and ability to pay, thought to be relevant to access the needed medical care. In theory, to evaluate their success in obtaining appointments, it might be possible to recruit real patients in need of routine examinations or care following emergency room visits, but the logistical difficulties in recruiting a sufficient number of patients with the right characteristics make this an impracticable option. Assuming that the research question posed by this and comparable studies is socially valuable, we see no practicable, nondeceptive alternative for obtaining scientifically valid results.

In assessing the ethics of simulated patient studies, it is important to recognize that the use of deception in this type of research is not necessarily incompatible with obtaining valid informed consent. For example, investigators trying to evaluate the prescribing practices of physicians in response to simulated patients posing with various clinical scenarios might solicit consent in advance from a group of physicians willing to participate in this sort of research (Kravitz et al. 2005). The prospective subjects could be told the purpose of the study and informed that if they gave their consent, at some point in the future they would be visited unannounced by a simulated patient who would gather research data (with the protection of confidentiality). The study would deploy deceptive research methods, but the subjects would have

authorized the exact nature of the deception in advance via the informed consent process. This would make simulated patient research analogous to double-blind, placebo-controlled drug trials, in which prospective subjects are informed that neither they nor the investigators administering the treatment will know whether subjects are receiving the study drug or an indistinguishable placebo. In both situations, although research interventions are undertaken that involve either deception or concealment, prospective subjects are informed of all the material information that they need to give their informed consent.

While this approach of soliciting consent to a simulated patient study may offer scientifically valid results with respect to testing some research hypotheses, it is questionable whether it would be feasible or methodologically satisfactory to answer research questions relating to access to medical care with the aim of drawing valid inferences about the general working of the health care system. The higher the proportion of prospective research subjects who are contacted and refuse consent is, the more likely that the study results will not accurately reflect the behavior of the population from which the subjects are selected. The consent rates obtained by simulated patient studies that used this consent mechanism raise serious concerns about selection bias that undermines the validity of the study results. In a British study of counseling practices of pharmacists to be visited by simulated patients seeking to purchase drugs for various conditions, only 27 percent of the approached pharmacists agreed to participate (Weiss et al. 2010). Another study with simulated patients reporting symptoms of mental disorders, which was designed to assess the prescribing practices of primary care physicians, obtained consent rates of 53 to 61 percent (Kravitz et al. 2005). While this may have been adequate for testing the study hypotheses relating to the impact of direct-to-consumer advertising on prescription practices, comparable rates of failing to obtain consent would raise serious doubts about the validity of the results of a simulated patient study aimed at evaluating the ability of patients to obtain medical appointments in the United States based on insurance status or ability to pay. The DHHS's simulated patient study of access to primary care that prompted controversy was an effort to study the performance of the U.S. health care system as a whole, something that requires a truly random sample in order to produce results that are internally valid and generalizable.

Minimizing Risks

A basic requirement of research ethics is to minimize the risks consistent with conducting scientifically valid research. In the case of simulated patient studies of access to medical care, the key to minimizing, if not eliminating, risk lies in scrupulously protecting the data in order to preclude the identification of the research subjects who respond to telephone calls and the medical clinics or physician offices that employ them. Effective measures that protect the confidentiality of research data obviate the risk that specific clinics or physicians' offices might be embarrassed or subject to legal or regulatory sanctions if they were identified as engaging in practices that appear discriminatory. Specifically, the protection of human subjects in a well-designed simulated patient study of access to medical care involves professional survey methods using trained and supervised research staff who collect data in a uniform, systematic manner from providers' office staff and develop an unidentifiable database for analysis. No personal information or identifiers are collected from the people who answer the phone. Calls are kept as brief as possible, and the data collection focuses on getting an appointment date and other information that is typical of what the office might give out to any new patient requesting an appointment. Office staff are not asked to do anything outside their normal job description. All the data are collected and protected according to standard procedures and are analyzed in the aggregate without any reference to the individual provider's information. Finally, all identifying information is destroyed at the conclusion of the study.

Assuming adequate protections for privacy and confidentiality of research data are in place, there is no prospect of harm to those study participants whose involvement is limited to brief telephone conversations relating to obtaining appointments. Nor is there any prospect of harm to the medical practices whose appointment policies are being investigated, as they remain unidentified and unidentifiable. Although deception is employed, the deceptive interaction is slight. Those who participated in the research unwittingly may come to know that their office was within the sampling frame of the research as a result of a debriefing letter sent to clinics and medical practices. But they would not know whether they personally were contacted by simulated patients, and even if they did come to know this, any resulting sense of violation of trust would likely be minimal.

Justification for Waiving Informed Consent

Building on the points concerning scientific validity and minimizing risks, a formal ethical argument in favor of simulated patient research concerning access to medical care without consent can be developed as follows: While the investigators have a general obligation to obtain informed consent for interventional research, this obligation should not be construed as absolute. Like other moral obligations, the obligation to obtain informed consent can be overruled by sufficiently compelling social and scientific value of those research methods obtained without consent, provided that there is no feasible alternative consistent with valid consent. It is important to recognize that various types of obligations, and various instances of particular types of obligations, differ in their moral stringency (Sinnott-Armstrong 2009). For example, because consent is a vehicle for the voluntary assumption of risks, the obligation to obtain informed consent for interventional research has less moral stringency if the research poses only minimal risks than if the risks are high. The less strong a particular instance of an obligation is, the less compelling the countervailing considerations need to be in order to outweigh or overrule it.

Applying these general premises to simulated patient studies comparable to our case study, we submit that the obligation to obtain informed consent and the obligation not to deceive research subjects carry less weight in this context. Arrayed against these relatively weak obligations in this sort of research scenario is the considerable potential of the knowledge to be gained from such health services research, knowledge that is unlikely to be obtained when the results are confounded by the selection bias that would be created if consent were solicited before stating whether an appointment was available. We conclude that as long as adequate protections for confidentiality of data are in place, this form of minimally intrusive simulated patient research investigating the health care system without the consent of individuals working in that system can be ethically justified.

Although simulated patient health services research that protects the identities of human subjects is justifiable without consent, the question remains whether a *nonstandard* consent process might be substituted for the conventional solicitation of informed consent and whether that could also generate valid results. One possibility is to consider an opt-out consent mechanism in which individuals in the sampling frame for

a simulated patient study are notified about a forthcoming study and prospective subjects are offered the opportunity to refuse to participate by dialing a telephone number or logging on to a website. We anticipate that this would achieve a much higher rate of research participation than the standard soliciting of opt-in consent. Yet the very fact that it is likely to do so raises doubts about the validity of consent under this method. Some prospective subjects may never receive the notice; others might throw it out without reading it. In this circumstance, a lack of refusal does not necessarily imply consent.

We will not explore in greater depth here the merits of and problems with opt-out consent, because there are reasons to doubt its applicability to many simulated patient studies of the health care system. The fact that IRBs typically consider the receptionists or staff members—whose job it is to answer questions and schedule patients according to the expectations of their employers—to be the research participants creates additional problems for an opt-out consent mechanism. Chief among these is whether participation in this sort of socially valuable, systemwide research should rest with the decisions of support staff. If consent was given instead at the level of the medical provider or administrator whose health system is being evaluated, then support staff would still be enrolled in the research without themselves being given an opportunity to refuse to participate.

Nevertheless, it is possible that an opt-out mechanism may be relevant and offer a fair opportunity to refuse consent in simulated patient studies that directly interact with the provider. Opt-out mechanisms are more appropriate when they require more time on the part of a research participant, or take time away from real patients, such as simulated patient studies involving actual visits to clinicians or pharmacists. As a general rule, the greater the interaction between researchers and subjects is, the stronger the claim is for some consent mechanism. This implies that simulated patient studies will fall along a spectrum, from those that do not require consent at all, to those for which opt-out mechanisms are sufficient, to studies that require the conventional solicitation of informed consent.

When consent is waived for simulated patient health services research, it still is possible to notify clinics or medical offices in advance about the chance of receiving calls from simulated patients; however, we do not regard this as ethically necessary in view of the minimal interaction with research subjects. In any case, this is not an ethical substitute for

informed consent and would not obviate the minor but justified ethical infringements in the use of deception and the absence of consent in these studies.

Government Sponsorship

The controversy over the DHHS's proposed simulated patient study of access to primary care raised charges of "government snooping" (Pear 2011). Does government sponsorship of this type of research have any ethical relevance? While government agencies have the authority to conduct audits of regulatory compliance, this is not the purpose of simulated patient research aimed at assessing access to medical care (Rhodes 2011). Setting aside partisan politics, we see no ethical concerns with the government sponsorship of simulated patient research, provided that the issues just discussed are adequately addressed. Indeed, government agencies that administer programs of health insurance have a legitimate interest and even an obligation to gather information concerning beneficiaries' access to medical care. Accordingly, DHHS was not "snooping"; it had appropriately contracted with an independent survey laboratory to gather policy-relevant knowledge on the primary care workforce capacity in the form of aggregate data without identifying the service providers (*Federal Register*, April 28, 2011), something that is well within ethical standards.

Regulatory Considerations

There has long been controversy over whether low-risk social science research should be overseen by IRBs governed by federal regulations to protect human research subjects (De Vries, DeBruin, and Goodgame 2004; Patullo 1985; Pettit 1992). We do not take a stand on this complex issue, as our focus is primarily on ethical considerations pertaining to simulated patient studies without consent. As we have pointed out, this type of health services research deserves ethical attention, regardless of policy questions relating to the proper regulatory approach to social science research. To be sure, with IRB oversight, there is the potential for arbitrarily disapproving or restricting valuable research. Conversely, significant ethical issues relevant to justifying social research, especially

when it involves deception and the absence of consent, may be ignored in the absence of IRB review or some comparable mechanism of independent oversight.

It is worth considering whether government-sponsored simulated patient research of access to medical care (or relating to other services) should also undergo ethical review. U.S. federal regulations governing human subjects research, which we examine in the following section, exempt from review by institutional review boards those "research and demonstration projects which are conducted by or subject to the approval of Department or Agency heads, and which are designed to study, evaluate, or otherwise examine: (i) Public benefit or service programs; (ii) procedures for obtaining benefits or services under those programs; (iii) possible changes in or alternatives to those programs or procedures; or (iv) possible changes in methods or levels of payment for benefits or services under those programs" (Code of Federal Regulations 45CFR46.101(b)(5), 2009). While IRB oversight would appear not to be required for the proposed DHHS-sponsored simulated patient study of access to primary care, we suggest that some form of independent review would be desirable to address the need to waive informed consent requirements to produce scientifically valid data and to ensure that risks to subjects are minimal and that adverse consequences to clinical and medical practices are prevented.

A threshold issue of regulatory jurisdiction is whether simulated patient studies even constitute human subjects research under the federal regulations, given that "observation of public behavior" does not meet the definition of research with human subjects (Code of Federal Regulations 45CFR46.102f, 2009). Indeed, a recently published report of a simulated patient study concerning the practices of pharmacies in providing access to emergency contraceptive medication stated that "the Boston University Medical Center Institutional Review Board deemed this study to be non-human subject research" (Wilkinson et al. 2012, 625). The current regulatory definition of "human subject" is the following: "*Human subject* means a living individual about whom an investigator (whether professional or student) conducting research obtains (1) Data through intervention or interaction with the individual, or (2) Identifiable private information. Intervention includes both physical procedures by which data are gathered (for example, venipuncture) and manipulations of the subject or the subject's environment that are performed for research purposes. Interaction includes communication or

interpersonal contact between investigator and subject" (Code of Federal Regulations 45CFR46.102f, 2009). Simulated patient studies of access to pharmaceutical products or medical care involve interaction with human subjects—the pharmacy, clinic, or medical office staff who respond to telephone calls from researchers posing as patients seeking information or appointments. Yet it might be argued that simulated patient research on access to medical care via telephone calls with receptionists at medical offices is not collecting data *about* the receptionists. Rather, it is collecting data about the appointment practices of these organizations. Conversely, this type of research is collecting data about the behavior of receptionists in scheduling appointments, thus arguably making them human subjects under the regulatory definition. We believe that there is room for debate as to whether an individual answering the phone on behalf of a business is the "research subject" when the goal of simulated patient studies is to study "business as usual" across a number of medical care organizations. Nonetheless, most IRBs that have reviewed studies employing the simulated patient method *do* classify it as collecting data on the behavior of human subjects. The rationale is that it constitutes a manipulation of the subjects' environment and involves communicative interaction between the researchers and the staff who speak on behalf of the business. They approve such studies when they believe that the design meets the regulatory conditions necessary for waiving consent. From an ethical perspective, this is desirable; otherwise, research involving deception and without consent could be conducted without the IRB's review and approval of the study protocol. But in view of the "public versus private" nature of studying the health system and the divergent IRB practices in applying the definition of "human subject" to simulated patient studies and other forms of mystery shopper research, it would be desirable for the U.S. Office for Human Research Protections to provide additional guidance on this issue.

The current regulations are as follows: The U.S. federal regulations permit IRBs to approve research without informed consent in some circumstances. Four conditions must be satisfied: "(1) the research involves no more than minimal risk to the subjects; (2) the waiver or alteration will not adversely affect the rights and welfare of the subjects; (3) the research could not practicably be carried out without the waiver or alteration; and (4) whenever appropriate, the subjects will be provided with additional pertinent information after participation" (Code of Federal Regulations 45CFR46.116d, 2009).

The case study of simulated patient research on access to medical care qualifies for each of these requirements. The minimal intervention with subjects and the data confidentiality make the study no greater than minimal risk. It might seem impossible for simulated patient studies to satisfy the second condition, as they do infringe on rights not to be deceived and to be free of research interventions without consent. Strict interpretation of this regulatory provision, however, would rule out all studies employing deception or conducted without consent, which would defeat the purpose of permitting IRBs to approve studies that deviate from a requirement of informed consent. We suggest that the second condition be interpreted as holding that the waiver of consent does not unreasonably infringe on the subjects' rights. The simulated patient study would easily qualify under this interpretation. Also, posing no (or, at most, minimal) risk to the subjects, it does not adversely affect their welfare. We argued earlier that scientifically valid data for this type of study, aimed at investigating the health care system, cannot be obtained with the standard practices of soliciting consent. Finally, our case study used a debriefing mechanism that satisfies the fourth condition. Arguably, the publication of results could also be construed as meeting this obligation.

Conclusion

Simulated patient studies conducted as health services research pose ethical concerns related to the deception and absence of consent that deserve careful attention. We contend that such studies are ethically justified and can be approved under U.S. federal regulations without consent when (1) they expose research participants to no more than minimal risks or burdens; (2) the waiver of consent is necessary to produce scientifically valid data; and (3) the potential social value of the knowledge to be gained from the research is substantial.

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